

REMARKS

(1) Applicants have amended the specification to include reference numeral **32**, the numeral corresponding to the longitudinally disposed groove as recited in the specification at page 19, paragraph 80, and in originally filed claim 12.

Applicants have replaced drawings sheet 10/13 (Figure 10) with a Replacement Sheet 10/13. A marked-up (in red) copy is attached to this response for the benefit of the Examiner (Annotated Sheet).

(2) Claims 13-14 and 34-50 are pending in the application.

Claims 13, 34, 43, and 44 have been amended to be in compliance with MPEP 608.01(m).

Claim 13 has been amended to include the limitation of the groove (reference numeral 32) to not be in contact with the first elongate tubular body (reference numeral 1). Support for the amendment is to be found in the specification at page 19, paragraph 80, and in the drawings, Figure 10 as originally filed and in Figure 2C as amended in response filed 5 June 2008.

Claim 34 has been amended to include the limitation of the groove (reference numeral 32) to not be in contact with the first elongate tubular body (reference numeral 1). Support for the amendment is to be found in the specification at page 19, paragraph 80, and in the drawings, Figure 10 as originally filed and in Figure 2C as amended in response filed 5 June 2008.

No new matter has been added by these amendments. Applicants respectfully request entry of the present amendments.

Objections

(3) The Examiner objected to the claims because they included reference characters that are not enclosed within parentheses.

Applicants have amended the claims to include all the reference characters within parentheses in compliance with MPEP 608.01(m).

Applicants respectfully request that the Examiner withdraw the objection to the claims.

(4) The Examiner objected to the drawings as failing to comply with 37 CFR § 1.84(p)(5) because they did not include the reference sign(s) mentioned in the description: the groove of claim 1 was not shown in Figure 10 nor did the specification recite an element number for this groove. The Examiner required corrected specification and drawing sheets to avoid abandonment of the application.

Applicants have amended the specification and claims 13 and 34 to recite reference numeral 32 corresponding to the element of the groove. Applicants have provided replacement drawings in compliance with 37 CFR 1.121(d).

Applicants respectfully request that the Examiner withdraw the objections in the drawings and the specification.

Claim Rejections under 35 USC § 103(a)

5) The Examiner has rejected claims 13, 14, 37-42, and 45-50 under 35 USC § 103(a) as being unpatentable over Noda et al. (USPN 6,726,653) in view of Knowlton (USPN 6,427,089).

Regarding claims 13, 14, 42, and 45-50, the Examiner stated that Noda et al. discloses the heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject. The Examiner

stated that Figure 8 of Noda et al. disclosed a balloon that, when inflated had a longitudinally disposed groove upon its outer surface. However, the Examiner continued, Knowlton discloses a stomach treatment apparatus with an ultrasound transducer used to image the device distal end. Therefore, the Examiner concluded, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Noda et al. as taught by Knowlton, to provide means to image and therefore, locate and position the treatment apparatus as required by the procedure.

Regarding claims 34-36, the Examiner stated that Noda et al. disclose the method essentially as claimed, wherein the cooling rates could be obviously be determined by a skillful artisan without undue experimentation.

Regarding claims 37-40, the Examiner stated that Noda et al. disclose wherein the second elongate tubular body is disposed longitudinally within the first elongate tubular body, wherein the subject is a human subject, wherein the anatomical structure can be the esophagus and the target organ be the heart, wherein the balloon is shaped and sized for placement in the anatomical structure, and wherein the target organ is selected from the group consisting of: the myocardium of the heart, the lungs, the thymus, the thyroid, the liver, the pancreas, the kidney, the uterus, the ovary, the testis, the prostate, and the brain.

Regarding claims 41 and 45-50 the Examiner stated that the claim limitations are directed to an intended use of the device rather than a structural modification and the Noda et al. device would obviously be capable of providing the claimed cooling rates.

Regarding claim 43, the Examiner maintained that it would have been obvious to one of ordinary skill in the art to provide a guiding catheter or sheath over at least a portion of the first elongate tubular body to assist in positioning the catheter within the patient's body as is well known in the art.

Regarding claim 43, the Examiner maintained that it would have been obvious to a skilled artisan to provide a pill (digestive composition) at the end of the guide wire to

assist the patient in swallowing the guide wire at the beginning of the method or procedure.

(6) The Examiner noted that Applicants' arguments with respect to all pending claims had been considered but were moot in view of the new grounds of rejection. The Examiner observed that in the independent claims if the depth of the groove on the surface of the balloon were limited in depth so as not to be in contact with the first elongate tubular structure, the these claims would be allowable over the reference cited therein

(7) In accordance with the Examiner's statement above in section 6, Applicants have amended claim 13 to recite: "A heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising: (a) a first elongate tubular body (1) having a proximal end and a distal end, (b) a second elongate tubular body (2) having a proximal end and a distal end, (c) a balloon (4) defining a lumen (8) in fluid communication with both the first elongate tubular body (1) and the second elongate tubular body (2) so as to form a continuous fluid pathway, further comprising a third elongate tubular body (3) having a proximal end and a distal end, the third elongate tubular body disposed longitudinally within the second elongate tubular body, and wherein the balloon is sealably affixed to the outer surface of the first elongate tubular body and sealably affixed to the outer surface of the third elongate tubular body, the lumen (8) further comprising a thermal exchange composition, wherein the thermal exchange composition is disposed within the continuous fluid pathway formed by the second elongate tubular body (2), the first elongate tubular body (1), and the balloon lumen (8) and wherein the thermal exchange composition is selected from the group consisting of a solid, a gel, a liquid, and a gas, and (d) a transducer (29), and wherein the balloon (4), when inflated, has a longitudinally disposed groove (32) upon its outer surface, wherein the groove (32) is not in contact with the first elongate tubular body (1) and the balloon (4) is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner

surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled”. Applicants submit that Noda et al. teach a groove that is in contact with a first elongate tubular body.

Applicants respectfully submit that the claimed structure is different from that taught by Noda et al. (Noda et al. Figure 8) in view of Knowlton and therefore claim 13 would not have been obvious to one of skill in the art at the time of the invention. Applicants submit that claim 13 is therefore not unpatentable over Noda et al. in view of Knowlton.

Applicants also submit that dependent claims 14, 37-42, and 45-50 are therefore not unpatentable over Noda et al. in view of Knowlton.

Applicants respectfully request that the Examiner withdraw the rejection of claims 13, 14, 37-42, and 45-50 under 35 USC § 103(a).

(8) In accordance with the Examiner’s statement above in section 6, Applicants have amended claim 34 to recite: “A method of altering the temperature of the myocardium of the heart in a subject, the method comprising the steps of: placing a heat exchange catheter system into the esophagus of a subject, wherein the heat exchange catheter system is adapted for placement within an anatomical structure of a subject, and comprises (a) a first elongate tubular body (1) having a proximal end and a distal end, (b) a second elongate tubular body (2) having a proximal end and a distal end, (c) a transducer (29), (d) a marker (31), and (e) a balloon (4) defining a lumen (8) in fluid communication with both the first elongate tubular body (1) and the second elongate tubular body (2) so as to form a continuous fluid pathway, further comprising a thermal exchange composition within balloon lumen (8), wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body (2), the first elongate tubular body (1), and the balloon lumen (8), and wherein the balloon (4), when inflated, has a longitudinally disposed groove (32) upon its outer surface, wherein the groove (32) is not in contact with the first elongate tubular

body (1) and the balloon (4) is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled; and circulating the thermal exchange composition within the continuous fluid pathway, whereby the myocardium of the heart is cooled". Applicants submit that Noda et al. teach a groove that is in contact with a first elongate tubular body.

Applicants respectfully submit that the structure used in the claimed method is different from that taught by Noda et al. (Noda et al. Figure 8) in view of Knowlton and therefore claim 34 would not have been obvious to one of skill in the art at the time of the invention. Applicants submit that claim 34 is therefore not unpatentable over Noda et al. in view of Knowlton.

Applicants also submit that dependent claims 35 and 36 are therefore not unpatentable over Noda et al. in view of Knowlton.

Applicants respectfully request that the Examiner withdraw the rejection of claims 34-36 under 35 USC § 103(a).

CONCLUSION

With the above amendments and additional remarks, Applicants submit that the instant application is now in condition for allowance.

If the US Patent Office believes that communication would further the prosecution of this application, then the appropriate US Patent Office personnel are invited to contact the Applicants' below-signed representative at their earliest convenience.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Bell & Associates Deposit Account No. 50-3194.

Dated and signed:

5th May 2010



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